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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,637	02/23/2004	Joseph P. Errico	F-270	8185
51640	7590	09/25/2009		
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 09/25/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,637	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Note to Applicant that the petition to correct the claim to priority is under review.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "the at least two tines" in line 17 of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim only recited **a pair** of tines. Claims 18-24 depend from claim 17.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note the effective date is the filing date for this application.

Claims 1-6,13-19,21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Krueger et al. (2004/143332). Fig. 1 shows a spinal implant having two baseplates **102**, **106** and includes a coupling member **104** to permit articulation about ball surface

Art Unit: 3738

130. There is also shown (Fig. 32) an insertion tool **238** that has a shaft **240** with a distal end and a longitudinal axis. The apparatus for inserting a disc implant also includes at the distal end of the tool at least two tines **242** with top and bottom surfaces forming a central pocket therebetween as seen in Fig. 32. Krueger et al. additionally show (Fig. 33) the insertion apparatus assembled with the tines being forward of the shaft distal end and inserted between the baseplates to substantially fill a height of a separation space volume between the baseplates and keep the plates in a substantially parallel orientation to one another and engage corresponding surfaces. Fig. 33 also illustrates the tines contact the inward surfaces of the baseplates. Regarding claim 2, it can be seen at least one baseplate has a spike **108**. With respect to claim 3, Fig. 31 shows a spinal insertion tool having a handle **234** to apply pressure. Regarding claims 4,18 Fig. 32 shows the apparatus for insertion includes a stop **248** to prevent over-insertion of the tines. With respect to claim 5, Fig. 33 shows the tines end are angled such that it can be considered tapered. Regarding claims 16,24 there is only one ball and socket **132** Fig. 2) and is thus a single coupling. With respect to claims 14,15,22,23, Figs. 14,15 show the implant can comprise a post structure **146** that projects up from one baseplate and ball component **178** has an opening **148** to receive the post.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7,8,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger et al. (2004/0143332). Krueger is explained supra. However, Krueger fails to disclose the tines of the tool have a lower curved contact surface and a flat upper surface and to correspond with baseplate structures. It would have been an obvious to one of ordinary skill in the art to modify the corresponding engagement surfaces of the tines and baseplates, since such a modification only involves routine skill in the art, and would not materially affect the operation of the implant. Thus an engineer in developing the implant and tool can easily modify the contours of the tines and baseplates taught by Krueger et al. to be flat and curved corresponding surfaces as claimed in claim(s) 7,8,20 since such a coupling of the apparatus keeps them together or in other words matching contours.

Response to Arguments

Applicant's arguments filed 1/27/09 have been fully considered but they are not persuasive. Applicant on page 3 of the remarks states that Krueger (Fig. 52) includes two sets of tines. However, the Examiner is confused as there is no such figure in the Krueger reference, as it only has 43 figures. The Examiner thought the Applicants meant to comment about Fig. 32. In response to applicant's argument that the Krueger references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the claimed spinal tool has only one set of tines) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See

Art Unit: 3738

In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In fact claim 1 recites at least two tines.... which clearly implies that there can be more than one set of tines, i.e. two sets, three sets, four sets etc. Thus, Applicants argument contradict the scope of what the claim encompasses. Additionally, the comments about Krueger having more than a pair of tines is incorrect, especially in view of Fig. **32** which clearly shows only two tines. Applicants also argue the tines of the claimed invention are tapered as recited in claim 5 and that Krueger has tines that are flat. While the figures may illustrate the top and bottom surfaces appear flat, the figures also show the ends being tapered. The claims do not define what surfaces are tapered and thus in giving the broadest interpretation, it can be said that the tines are tapered.

Applicants then argue that the obviousness rejection was not understood in modifying the surfaces. The Examiner in clarifying his position would like to state that it is obvious to one of skill in the art in using instruments to engage a structure that the most accurate control is when the surfaces match such that no movement occurs other than what is desired by the person or surgeon positioning the structure. For example hex nuts are turned by an appropriate box wrench. Thus, it would not be appropriate to match a rounded surface with a flat surface or an angled surface. A concave surface is appropriate to receive a convex structure therein and vice versa. The same is true with an angled edge would be appropriate with an angled protrusion that would match its surface. Therefore the Examiner was suggesting it is a basic concept within the skill of the normal artisan in designing tools to match implant surfaces to have them match.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738